

**REMARKS**

**I. 35 USC 103(a)**

Claims 14, 16, 17, 19-27 and 29-32 are rejected under 35 USC 103(a) as being unpatentable over Keyes (US 4,169,765) in view of Yamagishi et al. (US 6,730,212 B1). The Applicant respectfully traverses this rejection as follows.

Claim 14 recites the following:

*A method for determining an organism, the method comprising assaying a plurality of enzymes with a sensor to determine a suite of enzymes expressed by the organism, and thus determining said organism; the sensor comprising: a substrate; more than one pair of electrodes; a sol gel matrix comprising: more than one sol-gel enzyme; at least one reactant; and at least one inherently conductive polymer transducer material, wherein each of the more than one sol-gel enzymes is associated with at least one of the more than one pair of electrodes; wherein (a) an organism expresses at least one organism-enzyme on the surface of the sensor; (b) the at least one organism-enzyme causes a reaction with the at least one reactant of the sensor; (c) the product according to process step (b) reacts further with said more than one sol-gel enzyme of the sensor; (d) the products of process step (c) modulate at least one property of the transducer material; (e) and the modulated property is measured.*

Keyes discloses a method for the detection of the  $\alpha$ -amylase enzyme from an organism using a sensor.

Yamagishi et al. discloses a sensor comprising a glass substrate having interdigitated electrodes covered by a sol-gel matrix comprising one enzyme (col 3, lines 36-40).

At page 5 of the pending Office Action, the Examiner states, *"It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the enzyme immobilized sensor method ...as taught by Keyes...with the enzyme-encapsulated, conductive polymer sol-gel biosensor as taught by Yamagishi et al..."*. The Applicant notes that the resulting method from the combination of Keyes and Yamagishi et al. would be a sensor having one "detecting" enzyme. The combination of Keyes and Yamagishi et al does not produce nor render obvious the presently claimed method for *assaying a plurality of enzymes with a sensor... comprising... more than one sol-gel enzyme*, as recited above in claim 14 because neither reference teaches or suggests a method using more than one enzyme.

At page 6 of the pending Office Action, the Examiner alleges, *"If the prior art structure is capable of performing the intended use, then it meets the claim."* The Applicant notes that the prior art structure itself is irrelevant in view of the fact that neither Keyes nor Yamagishi et al. discuss the presently claimed method of assaying a *"plurality of enzymes with a sensor...comprising...more than one sol-gel enzyme..."*. In fact, Keyes teaches a method for the detection of specifically and only  $\alpha$ -amylase. In view of Keyes, one skilled in the art of enzyme detection reading Yamagishi et al, would appreciate the encapsulating properties of the sol-gel matrix, and should the skilled person want to assay a plurality of enzymes from an organism, reading the sensor description at col 4, lines 44-64 of Yamagishi et al., the skilled person would not put multiple enzymes on one sensor, but instead would combine multiple sensors in

one assembly (see specifically lines 47-48 and the sensor (100) of Figure 1). In contrast, claim 14 recites a method for *"assaying a plurality of enzymes with a sensor...comprising...more than one sol-gel enzyme..."*. Figure 1 of the originally filed present application shows a variety of sol-gel enzymes (5) on one sensor. Comparing Figure 1 of Yamagishi et al. with Figure 1 of the present application it is clear that though the structures of the sensors are similar, the sol-gel matrix enzymes placed thereon are shown differently. Yamagishi shows the sol-gel enzyme (4) as one type of enzyme, while the present invention shows the sol-gel enzyme (5) as various types (shapes). Thus the sensor of Figure 1 of Yamagishi together with the suggestion at col. 3, lines 47-48 to combine multiple sensors would provide the skilled person wanting to assay a plurality of enzymes with, at most, a method of assembling *multiple* sensors having different sol-gel enzymes. The presently claimed method of more than one enzyme on a same sensor is not discussed nor shown in any of the structures disclosed by either Keyes or Yamagishi et al, and furthermore, these references taken independently or in combination teach directly against the presently claimed method of utilizing a single sensor.

At page 7 of the pending Office Action, the Examiner alleges *"As the combination of Keyes and Yamagishi et al. disclose an enzyme sol-gel immobilized sensor method using a single electrode, it would have been obvious to combine an array of multiple organism enzymes in one assay..."*.

The Applicant respectfully disagrees with the Examiner's rejection that a multiple enzyme sensor is obvious and traverses this conclusion as falling short of the requirements for a proper 35 USC §103 rejection as set forth in the MPEP as well as the new KSR v. Teleflex Examination Guidelines of October 10, 2007.

Perhaps the most instructive portion of the Guidelines is the clear statement that *"The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s)*

*why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn stated that “ [R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”* The Applicant notes that the Examiner has provided conclusory statements that the skilled person would have produced the claimed method using more than one enzyme on a sensor, when in fact, as discussed above, the skilled person is not likely to arrive at this method in view of Keyes and Yamagishi et al. The obviousness rejection is based on the Examiner's unsupported opinion of what the skilled person would allegedly have done.

The Guidelines do make clear that *“the familiar teaching-suggestion-motivation (TSM) rationale”* can still be employed by Examiners in making an obviousness rejection. However, as noted above, the Applicant has pointed to clear disclosure in Yamagishi et al. that the skilled person could assemble multiple sensors. This is contrary to the presently claimed method comprising one sensor with more than one enzyme. The Applicant further notes that while multiple approaches could be obvious in view of the cited references, one skilled in the art of detecting organisms using an enzyme assay would indeed find it easier to assemble multiple sensors, than to apply more than one enzyme onto one sensor.

In view of the above, the Applicant submits that claims 14, 16, 17, 19-27 and 29-32 are patentable under 35 USC 103(a) over Keyes in view of Yamagishi et al.

## **II. Conclusion**

The Applicant has complied with each and every requirement in the pending Office Action, and requests allowance of the pending claims. All remarks herein are made without prejudice.

The Commissioner is authorized to charge any additional fees that may be required or credit overpayment to deposit account no. 12-0415. In particular, if this response is not timely filed, the Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 CFR §1.136(a) requesting an extension of time of the number of months necessary to make this response timely filed, and the petition fee due in connection therewith may be charged to deposit account no. 12-0415.

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